

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1 to 15, 22, 23, 25 and 26 are pending with entry of this amendment. claims 16 to 19, 24 and 27 to 66 being cancelled. Claims 1 and 7 are currently amended. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claim 1, support for continuous phase aqueous matrices of cross-linked proteins, not cross-linked using an added divalent linker agent can be found throughout the specification. For example, see the Matrix Suspension section starting at paragraph 69, the Heat Treatment section starting at paragraph 89, and in the Examples. Applicants note that "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). At paragraphs 8, 10 and 89 of the specification, the use of cross-linking agents is positively recited as a possible, if often undesirable, alternative method of cross-linking proteins. Because linkers are positively recited specifically and generically in the original specification, controlling case law holds the negative limitation amendment to be proper.

With regard to claim 7, the amendment further clarifies that the specific surface area of droplets is in the composite gel, as described in the original specification at paragraph 86, and in the Examples.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

The Information Disclosure Statement.

Applicants note with appreciation the Examiner's thorough consideration of the references cited in the Information Disclosure Statements (Form 1449) submitted on December 8, 2003, April 22, 2006, April 5, 2007 and August 13, 2007.

Interview Summary.

The Office graciously granted a telephonic Interview in this case on May 7, 2008. Discussions between Applicant's representative, Gary Baker, and Examiner Mercier and SPE Woodward concerned a proposed amendment to claim 1.

Applicant's representative suggested the claim would be amended to require aqueous matrix protein cross-linking not be by linkers. Support was cited from the specification, and SPE Woodward suggested such an amendment would probably be considered supported. SPE Woodward indicated the anticipation rejection would probably be overcome, but the Office would have to review the art for further obviousness rejections. Applicant's representative noted that the current Rawlings obviousness reference teaches away from the present claims.

35 U.S.C. §102.

Claims 1-3, 8, 11, 13-15, 17 and 22-26 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kyogoku (U.S. 5,093,028). To the extent the rejection is deemed applicable to the amended claims, Applicants traverse.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. That is, in order for a reference to anticipate an invention, anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

Kyogoku teaches preparation of a sausage by cross-linking a protein gel around emulsified oil using a divalent iridoid cross-linker, such as genipin.

The invention in the currently amended claims specifically requires that the continuous phase matrix of cross-linked proteins not be cross-linked with a divalent linker. Because the Kyogoku does not teach all limitations of the independent claim, it can not be

said to anticipate the claims. Applicants respectfully request withdrawal of the rejections for alleged anticipation.

35 U.S.C. §103(a).

A proper analysis under the recently reaffirmed *Graham v John Deere* standard demonstrates the non-obviousness of the invention. According to the Supreme Court in *KSR International Co v. Teleflex* (550 U.S. ____ (2007); 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385-1396 (US 2007)), the appropriate standard for analyzing questions of obviousness is that:

the scope and content of the prior art are determined, differences between the prior art and the claims at issue are analyzed and the level of ordinary skill in the pertinent art is resolved. Against this background the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc. might be utilized to give light to the circumstances surrounding the origin of the subject matter to be patented.

Id. quoting *Graham v. John Deere of Kansas City* 383 U.S. 1, 17-18.

The current Examination Guidelines (Federal Register 72: vol 195 (October 10, 2007)) note that the teaching-suggestion-motivation (TSM) test was *not* overturned by *KSR*. The Guidelines and *KSR* require the Office in an obviousness rejection to provide a statement as to why one of skill would have combined known elements. In addition, the bulk of well established case law, such as described in MPEP 2143.01, still applies. For example, where the cited references teach away from the invention it is not obvious. The combination of references must teach all of the elements of the claims, the Office must provide a clear and articulated reason prompting one of skill to make the proposed combination (even where the outcome might be predictable), and there must exist in the art a reasonable expectation of success in any proposed combination. Here, the rejection fails each of these requirements, as applied to the *Graham* factors.

Claims are not obvious based on Kyogoku in light of Rawlings. Claims 4-7 and 20-21 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Kyogoku in light of Rawlings (U.S. 4,216,234). To the extent the rejection is deemed applicable to the amended claims, Applicants traverse.

As a preliminary matter, it is notable that Rawlings teaches away from the present invention by requiring a pH between 9.6 and 12.5 to form a gel. Therefore, Rawlings can not render obvious any of the claims, according to *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997), which holds that if a reference teaches away from the claimed invention in any material respect, the reference can not render the claims obvious and should not be cited in future obviousness rejections of the claims.

Further, specifically with regard to dependent claim 4, there is no fact-based statement in the Action that supports the rejection.

With regard to claim 7, Rawlings does not teach "lipid droplets compris[ing] a specific surface area of more than about 10 m²/ml of a filler phase in the composite gel." The Action states the "surface area of the lipid droplets would be a property of the particle size of the droplets" Applicants note that although droplet surface area may be proportionate to droplet size, this does not necessarily control the droplet surface area per volume of the overall composite gel. That is, this aspect can not be said to be inherent in the cited reference.

With regard to claims 20 and 21, Applicants note that Rawlings column 3, lines 3 to 6, cited in the Action, teaches that a gel can be formed by heating the aqueous medium at "a pH range from about 9.6 to 12.5". The present claims require the aqueous phase at a pH ranging from 4 to 9. Rawlings, at column 11 (and claim 1), teaches that no gel is formed at pH 9.4, but is formed at pH 9.6 and above. Therefore, Rawlings teaches away from the claims.

Claims are not obvious based on Kyogoku in light of Cook. Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Kyogoku in light of Cook (U.S. 5,428,072). To the extent the rejection is deemed applicable to the amended claims, Applicants traverse.

The Action acknowledges that Kyogoku does not teach linoleic acid, but notes that Cook mentions conjugated linoleic acid in the abstract. However, claims 9 and 10 are directed to composite gels of the invention wherein the lipid comprises a specific range of conjugated linoleic acid percent not taught in Cook. Because these limitations are not

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alleged in the Action (and are actually not found in Cook), no case is stated. The rejection must be withdrawn.

Claims are not obvious based on Kyogoku in light of Winowiski. Claims 18 and 19 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Kyogoku in light of Winowiski (U.S. 4,957,748). However, because claims 18 and 19 are currently cancelled, the rejections are moot.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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Respectfully submitted,



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Attachments:

- 1) A transmittal sheet; and,
- 2) A receipt indication postcard.